Bugg, Joy J.

From: Solana, Rick P.
Sent: Thursday, December 05, 2002 3:13 PM
To: Roethig, Hans; Patskan, George J.; Haussmann, Hans-Juergen; Sanders, Edward
Subject: FW:

Ted, you're so depressing!!! Thanks for the info. very helpful.

-----Original Message-----
From: Sanders, Edward
Sent: Monday, October 28, 2002 5:05 AM
To: Solana, Rick P.
Cc: Walk, Roger A.
Subject: FW:

Rick,

In our last conversation (with George and Richard) you mentioned that you had heard that it was possible that we could obtain information on PREPs regarding long-term health effects from the CDC or some other public health organization. I would like to assure you that this will not be possible at least for lung cancer and heart disease. My knowledge of COPD epidemiology is still not sufficiently extensive to be able to provide an opinion on that particular disease. There are two problems in attempting to carry out surveillance from collected data. The first is that such public health organizations do not obtain such data instantly. There is always a lag time of 2-3 years. Moreover, even after 1-3 years the data are not complete. The article below discusses the fact that for cancer, 99% of the data are not obtained for 4-17 years depending on the type of cancer. This problem is obviated by carrying out long-term surveillance through a prospective epidemiological study.

This problem, however, is minor compared to the problem that even after a relatively long time, even a large decrease in a particular disease risk would not be picked up by such data. Let's look at lung cancer as an example. Let's assume that we make a change to an existing product with a 30% market share, in other words a major product. Let us now assume that such product has a 60% reduction in lung cancer risk. We can divide the smokers of such product into two main equal groups. The first group consists of older smokers that already have a fairly long history of smoking. For this group (15% market share), the reduction in lung cancer risk would be about 30% on average after 10 years of smoking this product. This translates into a total decline in measured lung cancer risk of 15% times 30% or 4.5%. The other group would be younger smokers. After 10 years, the number of cases of lung cancer in this group would be too small to be detected. As a consequence, after waiting 10 years, a public health organization would have detected only a 4.5% decrease in total lung cancer. This number is much too small to be detected, given the inaccuracies in data collection. However, a 30% decline in risk after 10 years that would be picked up by prospective surveillance would be easy to detect. Moreover, as mentioned we are actually talking about 12-13 years because of the time delay. I won't work out an example for heart disease, but will just state that the problem here is the fact that smoking attributable heart disease mortality is only about 20%.

Therefore, long term surveillance is essential. Obviously at my age I am not seeking job security. If I have not made myself sufficiently clear, let me know.

Thanks.

Ted

-----Original Message-----
From: Badstuber, Andre
Sent: 28 octobre 2002 10:31
To: Sanders, Edward
Subject:

L132322.pdf

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Source: https://www.industrydocuments.ucsf.edu/docs/lndl0001

Le voilà.

PM3000398362

Source: https://www.industrydocuments.ucsf.edu/docs/lndl0001